REMARKS

In the Office Action of July 10, 2008, all claims were rejected, both on matters of form and matters of prior art, and the action was made final. A careful review of the Office action and the prior Office action has been made, along with the specification, the claims, and the prior art applied in the rejection, and it is believed that with a clarification of the claims, that the final rejection should be withdrawn, and a further consideration of this application should be made in view of the limited prior art before the effective filing date of this application, as the invention when properly understood and claimed, is clearly novel over the cited prior art and is also believed to be nonobvious, certainly as of the early date of the invention herein. Therefore, a Request for Continued Examination (RCE) has been filed along with this reply to the Office Action.

I. THE REJECTIONS ON NEW MATTER

In the final action, there were several rejections on new matter. One of these rejections is stated on page 5 of the Office Action and concerns Fig. 9. This passage was inadvertently copied from a prior Office action, as Fig. 9 was cancelled by a prior amendment. Therefore, this rejection is in error and it is respectfully requested that it be withdrawn in the next Office action.

The other rejection based on new matter was stated at page 6 of the Office Action based the recitation in claim 1 of:

> "the support shaft having an outer surface and a distal tip, wherein the support shaft has an electrically insulated cover on the outer surface between a first and second locations, the cover extending to the distal tip of the support shaft, ... first and second wire electrode sets extensible radially from the support shaft."

This rejection has many ambiguities. Is the Examiner objecting to :

1) recitation of the insulated cover?

2) recitation of the support as having a distal tip?

3) recitation of two positions relative to the first support shaft ?

4) recitation of the shaft itself?

or 5) all or some of the above items 1)-4)?

From the last sentence on page 6 it is believed that the sole basis for the rejection was the recitation of one shaft.

In fact, if the Examiner will refer to paragraph 0022 of the Specification, it will be seen that the configuration in Fig. 3 was identified as a "unitary shaft." For purposes of clarity, apparatus claim 16 now recites a "shaft configuration" as recited in paragraph 0042 of the specification comprising a first support shaft and a second support shaft.

II. SUPPORT FOR AMENDED CLAIM 1

1. (Currently amended) A method for ablating a volume of tissue in a patient comprising the steps of:

(a) inserting a first support shaft through the patient's skin, the first support shaft having an electrically insulated outer surface;

Support:

[Spec. para. 0028: Each electrode assembly 16a and 16b has a thin tubular metal shaft 18a and 18b sized to be inserted percutaneously (note: under the skin) into the liver 10.]

[Spec. para. 0029: Umbrella electrode assemblies 16a and 16b of this type are well known in the art, but may be modified, in one embodiment of the invention, by providing electrical insulation to all outer surfaces of the shafts 18a and 18b, ...]

[Spec. para. 0040 and 0041: Shafts 18c and 42 are typically metallic and thus are coated with insulating coatings 45 and 46, respectively to ensure that any current flow is between the exposed wires 32 rather than to shafts 18c and 42.

[0041] As mentioned above, this insulating coating 46 is also applied to the tips of the shafts 18a and 18b of the electrode assemblies 16a and 16b of Fig. 1 to likewise ensure that current does not concentrate in a short circuit between the shafts 18a and 18b but in fact flows from the wires 32 of the wires of electrodes 22a and 22b.]

Conclusion: The first support shaft is inserted under the skin and has an insulated outer surface as claimed.

Claim 1: (b) the first support shaft being inserted with a second support shaft through the patient's skin;

Support: What has been said about insulating the outer surface of the first support also applies to the second support shaft. Subparagraph (b) of claim 1 is intended to bring within its scope both the two insertions described in para. 0015 and the single insertion being described below in paragraph 0040:

[Spec. para. 0040: Referring now to Fig. 3, the difficulty of positioning two separate electrode assemblies 16a and 16b per Fig. 1 may be reduced through the use of a unitary electrode 40 having a center tubular shaft 18c holding within its lumen, the wires 32 of first electrode 22a and a second concentric tubular shaft 42 positioned about shaft 18c and holding between its walls and shaft 18c wires 44 of the second electrode 22b.]

Claim 1: c) radially extending at least three electrode tips in a first electrode set from the first support shaft at a first position along the first support shaft to three respective radial points defining a first plane surrounding the first support shaft, wherein the first position is spaced a distance from a center of the volume of tissue to be ablated, and wherein the second support shaft has a portion at a second position that is axially displaced by a predetermined distance from the first position;

Support:

Paragraph 0015 describes the extending the electrode wires to radial points defining the first plane and the second plane and the separation of the planes by a predetermined separation through the tumor (tissue) to be ablated.

Spec. para. 0015: The present invention also provides a method for ablation of a tumor volume in a patient comprising the steps of inserting a first electrode having a first support shaft and a first umbrella electrode set percutaneously at a tumor volume so that the first umbrella electrode set is at a first location adjacent to the tumor volume and offset from a center of the tumor volume, inserting a second electrode having a second support shaft and a second umbrella electrode set percutaneously at a tumor volume so that the second umbrella electrode set is at a second location opposed and at a predetemined separation from the first location and about the tumor volume, and extending the first and second umbrella electrodes sets radially from the first and second shafts to an extension radius wherein the electrode wires of the first umbrella electrode set are provided at radial points defining a first plane and the electrode wires of the second umbrella electrode are provided at radial points defining a second plane.

Comment: The electrode wires are further illustrated in Fig. 3 as having tips and are described in paragraph 0022 as having tips as follows:

[0022] Fig. 3 is a fragmentary cross-sectional view of a tip of a combined electrode assembly providing for the first and second electrode wires of Fig. 1 extending from a unitary shaft arranging the wires of the first and second electrodes in concentric tubes and showing insulation of the entire outer surface of the tubes and the tips of the electrode wires.

The axial displacement of the electrode sets is described in paragraph 0009 as follows:

> [0009] . . . By using axially displaced umbrella electrodes supported by outwardly non-conductive shafts, a large volume lesion area is created between two planes, and the entire volume between the planes is treatable. ...

The axial displacement is further described in paragraph 0018 as follows:

> [0018] Each of the assemblies in the kit includes first and second electrode sets which are offset an axial distance along a shaft and in which the electrode sets are radially extendible to a radial distance. The axial distance and radial distance of each electrode assembly in the kit is selected for a selected tumor size, thereby providing a series of electrode assemblies suitable for use in ablating tumors of various sizes, thereby providing a series of electrode assemblies suitable for use in ablating tumors of various sizes.

(d) radially extending a second at least three electrode tips in a second electrode set from the axially displaced portion of the second support to three respective radial points defining a second plane surrounding the second support shaft at the second position , wherein the second plane is opposite the first plane by a predetermined separation through the tissue to define a three-dimensional volume of tissue to be ablated; and

Support: For supporting subparagraph (d) including the "predetermined separation" please see the specification, paragraph 0015 explained above.

(e) in response to bipolar power being applied to the first electrode set and to the second electrode set, causing current flow between the first plane and the second plane and through the three-dimensional volume of tissue.

This is supported by paragraph 0015 of the Specification as follows:

Spec. Paragraph 0015: A power supply is connected between the first and second electrode umbrella sets to induce a current flow between them through the tumor volume whereby current induced heating is concentrated in the tumor volume defined between the first and second plane.

The reference to bipolar power is supported by paragraph 0009 in the following sentence: "The method overcomes the limitations of current electrode designs by adopting a multipolar electrode that increases the treatable tumor size."
Also, paragraph 0031 describes a voltage source of alternating current power which is a bipolar source. Paragraph 0047 states:" Importantly, although such frequencies may excite nerve tissue, such as the heart, such excitation is limited by the present bi-polar design."

III. SUPPORT FOR AMENDED CLAIM 16

16. (Currently amended) An electrode assembly for ablating tumors in a patient comprising:

(a) a shaft configuration comprising a first support shaft and a second support shaft, the first support shaft having an electrically insulated outer surface;

Support: The term "shaft configuration" is found in paragraph 0042 in describing the unitary or concentric configuration of Fig. 3 and the side-by-side configuration of Fig. 1. It should now be apparent that the specification describes insulating all exposed surfaces of the shafts and the electrode wires.

(b) a first electrode set having at least three electrode tips radially extensible from the first support shaft at a first position to three respective radial points defining a first plane surrounding the first support shaft;

Support: Paragraphs 0015, 0022 and 0029 cited above.

(c) a second electrode set having at least three electrode tips radially extensible from the second support shaft to three respective radial points defining a second plane surrounding the second support shaft at a second position that is axially displaced along the first shaft from the first position, wherein the second plane is opposite the first plane and is separated from the first plane by a predetermined separation to define a three-dimensional volume of tissue to be ablated between the first plane and the second plane; and

Support: Paragraphs 0015, 0022 and 0029 cited above. As to treatment volumes being "three-dimensional, " please see paragraph 0007, and this is also an inherent feature of a volume and is included in the claim for emphasis. As to the axial displacement, please see the excerpts from paragraphs 0009 and 0018 cited above.

(d) wherein when bipolar power is applied to the first electrode set and to the second electrode set, electrical current flows between the first plane and the second plane and through the three-dimensional volume of tissue.

Support:

Paragraph 0015: A power supply is connected between the first and second electrode umbrella sets to induce a current flow between them through the tumor volume whereby current induced heating is concentrated in the tumor volume defined between the first and second plane.

Paragraph 0038: "Current flows between electrodes 22a and 22b."

The reference to bipolar power is supported by paragraph 0009 in the following sentence: "The method overcomes the limitations of current electrode designs by adopting a multipolar electrode that increases the treatable tumor size."

Also, paragraph 0031 describes a voltage source of alternating current power which is a bipolar source. Paragraph 0047 states:" Importantly, although such frequencies may excite nerve tissue, such as the heart, such excitation is limited by the present bi-polar design."

IV. PATENTABLE DISTINCTIONS OF AMENDED CLAIMS 1 AND 16 OVER THE ART APPLIED IN THE REJECTION OF THE CLAIMS IN THE OFFICE ACTION OF JULY 10, 2008.

Claims 1-9, 13 and 16-27 were rejected over Gough, U.S. Pat. No. 5,728,143 and Gough, U.S. Pat. No. 5,683,384 and Swanson et al. , U.S. Pat. No. 6,488,679. Swanson et al. was applied to those portions of the claims reciting specific frequencies for applied power.

The present claims distinguish over the Gough patents in providing a basic volumetric ablation, using two electrode sets with at least three electrode tips each to define two spaced apart planes, an insulated support shaft between the two planes, and bipolar energization,so as to provide a volume of tissue ablation. While Gough, U.S. Pat. No. 5,728,143 and Gough, U.S. Pat. No. 5,683,384 mention volumetric ablation, this is by moving the trocar up and down, in or out of the patient or by rotating it (Gough '143, col. 4, lies 62-67; col. 8, lines 5-12; Gough '384 patent, col. 7, lines 52-65.)

The present invention teaches away from this technique and apparatus in paras. 0006 and 0007, in which the disadvantages of this art is discussed in requiring so much movement, including rotation of the electrodes within the patient.

The present invention of claims 1 and 16 is intended to provide a volumetric ablation without this movement by 1) using at least three electrode parts spaced around a shaft to define a plane; 2) using two such electrode sets, spaced apart to define a volume

and 3) providing an axial displacement of the first electrode set and the second electrode set to define a predetermined separation of the two electrode sets to define a treatment volume while removing the need to manipulate the electrodes simply to define a volume after initial insertion into the patient.

Paragraph 0009 summarizing the present invention states:

> **[0009]** The present inventors have developed a method for treating a tumor volume with improved efficiency while limiting the invasiveness of the treatment and improving treatment control. The method overcomes the limitations of current electrode designs by adopting a multipolar electrode that increases the treatable tumor size. Energy is focused on the tumor volume between two or more sets of electrodes, thereby simu1taneously treating a larger volume of tissue than was possible in the prior art. By using axially displaced umbrella electrodes supported by outwardly non-conductive shafts, a large volume lesion area is created between two planes, and the entire volume between the planes is treatable simultaneously. This method therefore provides an improvement over prior art monopolar and bipolar treatment methods, both in decreasing treatment time, and simplifyng control of the treatment.

The axial displacement is further described in paragraph 0018 as follows:

> [0018] Each of the assemblies in the kit includes first and second electrode sets which are offset an axial distance along a shaft and in which the electrode sets are radially extendible to a radial distance. The axial distance and radial distance of each electrode assembly in the kit is selected for a selected tumor size, thereby providing a series of electrode assemblies suitable for use in ablating tumors of various sizes, thereby providing a series of electrode assemblies suitable for use in ablating tumors of various sizes.

Claims 1 and 16 now recite a "axial displacement" and "a predetermined separation" of the first and second plane to overcome the disadvantages of the Gough methods of achieving volume ablation.

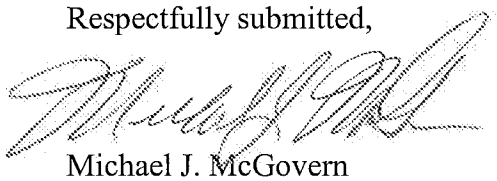
New claims 28 and 29 have been added to depend from claim 16 and recite two variants of the two-shaft configuration.

The remaining claims all depend directly or indirectly from claims 1 and 16 and are allowable for at least the same reasons as stated above.

SUMMARY

In view of the Amendment and Remarks and Request for Continued Examination, reconsideration of the application is respectfully requested. After the amendment, claims 1-9, 13, and 16-22 and 28-29 are still pending, and a Notice of Allowance for these claims is earnestly solicited.

Respectfully submitted,



Michael J. McGovern
Registration No. 28,326
BOYLE FREDRICKSON, S.C.
(Customer No. 23598)
840 North Plankinton Avenue
Milwaukee, WI 53203
Telephone: (414) 225-6317